



# COURAGE Chronicle

Courage Chronicle

March 2000

## “INTENSIVE” MEDICAL CARE versus USUAL MEDICAL CARE

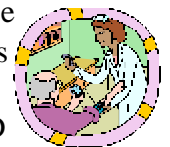
The purpose of the COURAGE Trial is to randomize patients with moderate to severe CAD, who have both evidence of ischemia and lesions amenable to PCI, to INTENSIVE MEDICAL CARE plus PCI or INTENSIVE MEDICAL CARE ALONE. This forms the basis for the only hypothesis that allows a fair comparison between the two arms of the study.

The **targets** for the intensive medical care and ischemic management are well delineated in the COURAGE Operations Manual: B/P < 130 mmHg / 85 mmHg; LDL between 60 mg/dL and 85 mg/dL; HDL > 35 mg/dL; and Hg1<sub>Ac</sub> at or below 7.0%. The COURAGE Trial also endeavors to prevent recurring ischemia and to provide for the secondary prevention of CAD. These targets and objectives are supported by the ACC/AHA *Guidelines for the Management of Patients with Chronic Stable Angina* and reinforced by the recently released results of the HOPE Trial. It is unlikely that “Usual Medical Care” will be sufficient to reach these goals. The medical therapy envisioned for the COURAGE Trial was designed to use the best available FDA-approved medications in ways consistent with the most recent results from randomized clinical trials for CAD patients in both arms of the study. The COURAGE Trial is thus encouraging its participating physicians and nurses to provide the best available care to their patients.

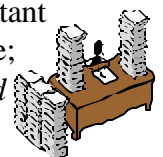
Moreover, several pharmaceutical companies have donated multiple top-of-the line, long-acting drugs for use in the intensive medical therapy of all enrolled patients. These drugs are all being prescribed for uses approved by the FDA, their long-acting characteristics facilitate the patient’s compliance with the prescribed dosage, and their donation to the study can provide substantial savings to the health care system, to the patient, and/or to the third-party insurer. The research pharmacist at one COURAGE site has **documented savings from donated drugs alone of \$83,924.88** for the 42 patients enrolled since the beginning of the trial on



June 28th, 1999 through March 9th, 2000. At first glance this may seem exaggerated, but it is in line with the Merck-Medco Managed Care data reported in the latest issue (March/April 2000) of *Health Affairs*, which reported a range of average annual expenditures on drugs of \$1,668 to \$2,055 (based on average wholesale prices) borne by elderly individuals with coronary disease for outpatient prescriptions, with annual expenditures of individuals in the 99th percentile ranging from \$7,174 to \$8,242.



The COURAGE Trial can provide state-of-the-art medical therapy for hundreds of CAD patients at costs subsidized by participating pharmaceutical companies *and* provide important scientific information that will shape the health care received by CAD patients for years to come; all we have to do is *enroll patients, provide the appropriate medical therapy, follow-up and counsel our patients, complete all forms and remit data promptly.*



## PRODUCTION OF THE COURAGE VIDEO COMPLETED

The final touches on the COURAGE video have been made. This video features four Coordinators recreating their presentations made during the waning hours of the Annual Meeting in San Diego. Pat Baker, Sandy Carr, Aimee Jacobs and Kendra Szymanski are engaged in an animated discussion relating their experiences in enrolling and counseling COURAGE patients. As soon as copies are ready for distribution, each site will receive a copy. The intended audience includes: COURAGE Coordinators and PIs (especially those new to the COURAGE Trial); fellows; residents; nuclear and cath lab techs; and referring physicians.

## ENROLLMENT IMPROVES

After the First Annual Meeting in San Diego, the weekly enrollment has generally improved. Before the meeting, the weekly average enrollment was just under nine per week. Beginning in February, the weekly rate has increased to over 15 per week; we are approaching the targeted goal of enrolling 21 patients per week.



*Luckily*, reaching that goal will become easier as new sites are added to the trial. We are happy to welcome Dr. Ralph Vicari, Mary Howard and Karen Koteek of MIMA Century Research Associates of Melbourne, Florida. They have now submitted all the required regulatory documents and can begin to enroll patients. Several potential new sites in the US and Canada are currently in the process of deciding whether the COURAGE Trial is a good fit with their available resources. Look for these new sites to join us soon. With these reinforcements, we expect that March enrollment, which began a bit *sheepishly*, to exit with a *roar* !



### Changing of the Guard at ECOR

Kate Hanson is now devoting all her efforts to the Nuclear Sub-Studies. Cheryl Lewis, BSN, has taken her place at ECOR, and will be handling Pentablot questions. Give her a call and say hello (404-712-1655)!

### SEND ECGs TO WEST HAVEN



Don't forget to have two original ECGs made. One stays with the patient's records; send the other (label on the back) to West Haven as soon after randomization as possible.

### REIMBURSEMENTS ...

... depend upon the up-to-date submission of all forms (including the ECGs), as well as those for the Angiographic Core Lab and ECOR.

## PATIENT ENROLLMENT UPDATE

671	Audie L. Murphy VAMC – San Antonio	42
506	Ann Arbor VA Medical Center	26
202	London Health Sciences Centres	26
580	Houston VA Medical Center	22
203	Montreal Heart Institute	22
<b>È WEEK 38: TARGET ENROLLMENT per SITE:</b>		<b>22</b>
558	Durham VA Medical Center	21
205	Queen Elizabeth II HSC	16
308	Mid America Heart Institute/Shawnee Mission	14
209	Sunnybrook & Women's College HSC	13
598	John C. McClellan VA – Little Rock	13
306	Mayo Clinic—Rochester	12
596	Lexington VA Medical Center	12
663	Seattle VA Medical Center	11
200	Foothills Hospital	11
304	Emory University Hospital	10
630	New York VA Medical Center	9
626	Nashville VA Medical Center/Vanderbilt Univ.	9
501	Albuquerque VA Medical Center	9
312	University of Michigan Medical Center	8
210	The Toronto Hospital	8
584	Iowa City VAMC/Univ. of Iowa Hospital	8
313	University of Oklahoma	7
211	University of Alberta Hospital	6
311	SUNY Health Science Center at Syracuse	5
508	Atlanta VA Medical Center	5
207	St. Paul's Hospital	5
302	Cleveland Clinic	4
201	Hamilton General Hospital, McMaster Clinic	4
301	Boston Medical Center	4
208	Sudbury Memorial Hospital	3
300	Barnes-Jewish Hospital	2
307	Christiana Care Health Systems	1
204	St. Michael's Hospital	1
212	Vancouver Hospital & Health Science Center	1

**Total Patients as of 03/17/2000: 370**

## Randomization Pager



There is now a COURAGE Pager for randomizations so that you can reach Ray at any time during working hours.

The pager number is: **888-473-4427**.

Try the regular numbers first, then the pager. Finally, if all else fails, open the next envelope and call West Haven as soon as possible.

